

Remarks

Claims 60, 61, 63, 65, and 67 are pending in the case.

The law regarding the requirements of the written description requirement has been summarized in the previous response and will not be reiterated here. Applicant will address specific points made in the Office Action dated October 16, 2008.

1. The Office notes that “[i]t must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is ‘not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.’” (Office Action mailed 10/16/08, p. 6, lines 5-9). However, the present molecule is not described “only by a functional characteristic,” and thus the reliance on this excerpt is out of place and not an appropriate basis for this rejection. To the contrary, the present invention is claimed entirely based on its structure. No claim recites only a functional characteristic. Thus it is seen that the legal basis of the rejection is without foundation.

2. The rejection continues to assert that “there is insufficient description of a common core structure that would allow one of skill in the art to practice the invention as claimed.” (Office Action mailed 10/16/08, p. 6, lines 14-15). But claim 60, the only pending independent claim, provides a very clear and obvious core structure. The components of R, R₁, R₇, and R₈ are indeed variable, but nevertheless supported by the specification and those of ordinary skill in the art would understand the inventors were in possession of the claimed invention. Indeed, examples of actual reduction to practice are included in the specification. And what is conventional or well known to one of ordinary skill in the art need not be disclosed in detail.

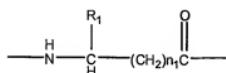
Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367 (Fed. Cir. 1986); 231 USPQ at 94.

3. The rejection also alleges that “...the examples in the specification are of a polymer that does not correspond to the formula [recited in claim 60].” But this is not correct when the claims are read correctly and the examples are understood. Attention is drawn to the example on p. 36, structure 13 disclosed in the specification (PCT WO 2004/061094), correspondence

between the core structure of claim 60 and what is disclosed in the specification is shown as follows:

Claim

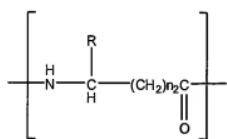
Y



Specification

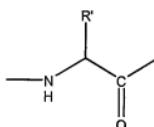
Y

~~~~~



X

$-\text{C}(\text{R}_7)(\text{R}_8)-$

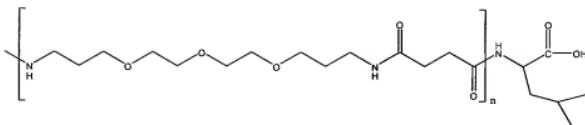


S



U





-Polymer

Polymer is further explained as follows:

It is first pointed out that the elements reciting group members of  $\phi$  and  $\psi$  are recited as "selected from the group consisting of," and thus any member of the group is within the scope of the claim. Additional possibilities specifically for  $\phi$  and  $\psi$  individually are also recited at the end of the claim element. Taking  $-\text{[NH-}\psi\text{-NH-C(O)-}\phi\text{-C(O)]}_n$  as "polymer" in the example its components are then  $\psi$  is  $-\text{(CH}_2\text{-CH}_2\text{-O)}_3\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-}$ , which is a specifically listed possibility in the claim, and literally supported at p. 14, line 28 of the specification (PCT Version). Then filling in the remaining  $-\text{NH-C(O)-}$  of "polymer" in the claim, unit  $\phi$  will be  $-\text{(CH}_2\text{-CH}_2\text{-)}$ , also a specifically listed possibility in the claim and literally supported at p. 14, line 27 of the specification (PCT Version). The  $\text{C=O}$  of Structure 13 then completes "polymer." Thus,  $n$  does not need to have a null value, as alleged in the Office Action (Office Action mailed 10/18/08, p. 7, lines 4-7).

It is therefore seen that Structure 13 of the claim does indeed fall within the scope of claim 60 and is well supported in the specification. The same can be done for Schemes 4 and 5 on pp. 37 and 38 of the specification. The synthesis of the same structure is also shown in Example 2 and is used in Examples 3 and 5 to synthesize various bioactive peptides. Persons of ordinary skill also recognize that chemical molecules are easily manipulated to closely related structures without comprising the intended function of the molecule. Thus, courts have recognized that what is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. *Id.*

Applicant has endeavored to be very specific in demonstrating that indeed an appropriate written description has been provided for the claimed invention, involving specific structural disclosures supported by actual examples. Since the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of

the invention as claimed, the written description requirement is satisfied. As illustrated by the various examples, the specification provides sufficient disclosure to appropriately support the generic claims made here, as the examples provided illustrate that the inventors were placed in possession of a genus.

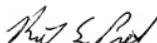
**Closing**

Applicants submit that the present response is complete and complies with the requirements of 35 U.S.C. §121, and that all claims are now in condition for allowance. Should the Examiner have any remaining questions regarding the subject invention or its patentability, Applicant encourages the Examiner to contact the undersigned to answer such questions or provide additional information.

Applicants believe that no fee is due in association with this response. If the Applicants are in error, the Commissioner is hereby authorized to charge any underpayment or credit any overpayment that may occur during the pendency of this application to Deposit Account No. 01-0535. Any required petitions not otherwise provided for herein are hereby constructively petitioned.

Dated: Jan. 16, 2008

Respectfully submitted,



Richard San Pietro  
Reg. No. 45,071

**AMYLIN PHARMACEUTICALS, INC.**  
9360 Towne Centre Drive  
San Diego, CA 92121  
Telephone: (858) 754-4981  
Facsimile: (858) 552-1936